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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------------|---------------------|------------------|
| 10/560,374   | 03/29/2007  | Kyu Chan Kwon               | CMT-0034            | 9097             |
| 23413 7590 03/30/2009<br>CANTOR COLBURN, LLP<br>20 Church Street<br>22nd Floor<br>Hartford, CT 06103 |             |                             |                     |                  |
| EXAMINER<br>DEBERRY, REGINA M  |             |                             |                     |                  |
| ART UNIT<br>1647   |             | PAPER NUMBER                |                     |                  |
| NOTIFICATION DATE<br>03/30/2009  |             | DELIVERY MODE<br>ELECTRONIC |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

### Office Action Summary

**Application No.**

10/560,374

**Applicant(s)**

KWON ET AL.

**Examiner**

Regina M. DeBerry

**Art Unit**

1647

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **Status of Application, Amendments and/or Claims**

The amendment and Applicant's arguments, filed 18 December 2008, have been entered in full. Claims 6 and 8 are canceled. Claim 1 is amended. Claims 1-5, 7, 9-11 are under examination.

### **Withdrawn Objections And/Or Rejections**

The rejection to claim 1-11 under 35 U.S.C. 103(a) as being unpatentable over Papadimitriou, US Patent 6,867,182 B2 in view of Yamazaki et al. (reference submitted Applicant; EP 0 909 564 B1) and Cheung et al., WO 00/61169 (reference submitted by Applicant), as set forth at pages 2-5 of the previous Office Action (22 September 2008), is *withdrawn* in view of the amendment and Applicant's arguments that the cited references do not specifically teach the use of 0.1-1.0% w/v of a sugar alcohol and 0.001-0.1% w/v of a polyhydric alcohol (18 December 2008).

### **NEW CLAIM REJECTIONS/OBJECTIONS**

#### **Claim Rejections - 35 USC § 102(e)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 7, 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Vukmirovic et al. (WO 2004/006958 A1).

Vukmirovic et al. teach aqueous pharmaceutical compositions comprising erythropoietin (EPO) (abstract, page 6 and claims). Vukmirovic et al. teach all forms of EPO including recombinant EPO (page 6-7 ; **applies to claim 2**). Vukmirovic et al. teach concentrations of EPO is from 1000 IU/ml to 100,000 IU/ml (page 7 and claims; **applies to claim 11**). Vukmirovic et al. teach buffering agents in the range of 1 mM-50 mM and a pH between 6-8 (page 7 and claims; **applies to claim 10**). Vukmirovic et al. teach isotonic reagents sodium chloride and calcium chloride and buffering reagents phosphate and citrate buffers. Vukmirovic et al. teach polyhydric alcohols such as glycerol and sugar alcohols such as mannitol and sorbitol and non-ionic surfactants in the range of .005-.5% w/v. Vukmirovic et al. teach neutral amino acids such as glycine at a concentration of 0.5% w/v (page 8 and 11 and claims; **applies to claims 1, 3, 5 and 7**).

**The Examiner notes that Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.**

#### **Claim Objections**

Claim 4 is objected to because it depends from a rejected claim.

#### ***Conclusion***

Claims 1-3, 5, 7, 9-11 are rejected

Claim 4 is objected to.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/  
Primary Examiner, Art Unit 1647

/R. M. D./  
Examiner, Art Unit 1647  
3/18/09